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Supreme Court, U.S.
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IN THE

Supreme Court of the United States

FESTO CORPORATION,

Petitioner,

—v.—

SHOKETSU KINZOKU KOGYO KABUSHIKI CO., LTD., a/k/a SMC CORPORATION and SMC PNEUMATICS, INC.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE MEDIMMUNE, INC. IN SUPPORT OF RESPONDENTS

HARVEY KURZWEIL
Counsel of Record
BRADFORD J. BADKE
HENRY J. RICARDO
DEWEY BALLANTINE LLP
1301 Avenue of the Americas
New York, New York 10019
(212) 259-8000

Counsel for Amicus Curiae MedImmune, Inc.

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STATEMENT OF INTEREST

MedImmune, Inc. ("MedImmune") is a biotechnology company based in Gaithersburg, Maryland.[1] MedImmune manufactures and sells Synagis®, a prescription drug that treats premature infants vulnerable to respiratory syncytial virus ("RSV"), the leading cause of infant hospitalization due to bronchitis and bronchiolitis. Synagis® contains "humanized" antibody molecules that help fight RSV. A humanized antibody molecule is a hybrid antibody that is created by combining human DNA with the DNA of another species (*e.g.*, a mouse). This combined DNA creates a hybrid (*i.e.*, "humanized") antibody molecule that is similar to the naturally occurring human antibody except for certain segments, derived from the mouse DNA, that appear in the naturally occurring mouse antibody that fights the same virus. Humanized antibodies serve as close substitutes for natural human antibodies, which are extremely difficult to reproduce in laboratory conditions.

MedImmune is the defendant in a lawsuit pending in the English High Court of Justice brought by the United Kingdom subsidiary of *amicus curiae* Celltech Group plc. (coilectively referred to as "Celltech"). Celltech has alleged that MedImmune owes it a royalty on sales of Synagis® pursuant to a license agreement between the parties that requires MedImmune to pay a royalty for sales of products that would infringe Celltech's U.S. patent but for the license.[2] Celltech has conceded that

[1] Written consent to the filing of this brief has been obtained from the parties and is lodged herewith. Counsel for a party did not author this brief in whole or in part. No person or entity other than the *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

[2] Although Celltech filed its case in England, Celltech has asserted that whether Synagis® falls within the scope of a valid claim of its U.S. patent is governed by U.S. patent law.

Synagis® would not literally infringe its patent. Celltech therefore relies entirely on the doctrine of equivalents to support its claim to royalties. MedImmune has sought dismissal of Celltech's suit on the basis that prosecution history estoppel prevents Celltech from relying on the doctrine of equivalents with respect to Synagis®. MedImmune's position is that prosecution history estoppel barred Celltech's claims both before and after the decision of the United States Court of Appeals for the Federal Circuit in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558 (Fed. Cir. 2000), and it will pursue dismissal of Celltech's suit as a matter of law regardless of how this Court rules in the *Festo* case. But before *Festo*, a patentee such as Celltech could construct a creative doctrine of equivalents argument that amounted to nothing more than an attempt to recapture the precise subject matter surrendered during prosecution. *Festo* has, or course, brought this tactic to an end.

SUMMARY OF ARGUMENT

Celltech purports to provide the Court with "a 'real world' example of how a licensee who entered into a pre-*Festo* license can use *Festo*'s complete bar to avoid paying very substantial royalties."[3] Cloaking itself with the concerns expressed by Judge Michel of the Federal Circuit in a concurring and dissenting opinion, Celltech warns that *Festo* would encourage licensees of biotechnology patents to engage in a two-step method for liability-free copying, working a great injustice against both Celltech in particular and licensors of biotechnology patents in general. Suggesting that it has befallen this fate, Celltech argues that it will lose the benefit of its license to MedImmune if *Festo* is affirmed. Regrettably, in its *amicus* brief Celltech has now provided this Court with a misleading account of the facts of its dispute with MedImmune, requiring MedImmune to submit this brief.

[3] Brief of *Amicus Curiae* Celltech Group PLC. in Support of Petitioner, at 2.

For the reasons set out below, an affirmance of *Festo* would have no such effect. Celltech has grossly mischaracterized MedImmune's development of Synagis®, the parties' expectations in connection with their license, and the scope of Celltech's patent rights in order to create the misimpression that *Festo* will cause an unjust result. In the process, Celltech has failed to advise the Court of the most important fact of all: that *Celltech obtained its patent only after amending its claims to exclude the specific feature found in the prior art and contained in Synagis® that it is now improperly trying to recapture under the doctrine of equivalents in its case against MedImmune.* Indeed, during prosecution, Celltech repeatedly distinguished its claimed invention from the prior art on the basis of the amendment at issue. This is a classic case of prosecution history estoppel under *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) and its progeny, in which a patentee attempts to use the doctrine of equivalents to recapture subject matter that it surrendered during patent prosecution.

While a reversal of the *Festo* decision would not breathe life into Celltech's case because of *Warner-Jenkinson*, Celltech's U.K. case is nonetheless an illustration of why greater certainty concerning the doctrine of equivalents would be of considerable value to prevent patentees from attempting to rewrite the prosecution history, and it supports an affirmance of *Festo*. Celltech admits, as it must, that there is no literal infringement.[4] Before *Festo*, patentees like Celltech would disclaim

[4] *Id.* at 7.

coverage of subject matter during prosecution in order to obtain allowance of their claims, only to advance creative arguments later in litigation in order to reclaim what was surrendered in the Patent Office. In the absence of *Festo*, a resourceful plaintiff such as Celltech would be able to force a defendant such as MedImmune to spend millions of dollars in legal and technical expert fees during discovery, claim construction proceedings, summary judgment motions, and perhaps even trial, to defeat an unmeritorious allegation of infringement under the doctrine of equivalents. By providing more certainty as to the scope of patent claims to patentees and competitors alike based on the public record, *Festo* prevents this kind of wasteful litigation.

ARGUMENT

I. CELLTECH HAS MISCHARACTERIZED THE FACTS OF ITS DISPUTE WITH MEDIMMUNE

A. MedImmune Did Not Engage in Copying and Has Not Reneged on its License Agreement with Celltech

Celltech paints MedImmune as an unscrupulous licensee that combed through the file history in search of a claim amendment to provide cover for a single insignificant alteration to Celltech's invention. Indeed, Celltech goes so far as to accuse MedImmune of "pirat[ing] Celltech's invention with impunity," and cheating Celltech out of its "vested rights" in the license agreement between the parties. Such allegations are unfounded.

In fact, MedImmune had already developed Synagis®, the life-saving drug that Celltech characterizes as the product of piracy, and performed clinical testing of it *before* Celltech's patent ever issued. As the Court is no doubt aware, Celltech's U.S. file history was not available to MedImmune until after the patent issued, so MedImmune had no opportunity to use it in the development of Synagis®.

Moreover, the *Festo* decision has *not* upset any settled expectations with respect to Celltech's license to MedImmune. Nowhere in this license agreement did MedImmune agree to pay a royalty in connection with sales of Synagis®, which belies any notion that the parties structured their agreement based on such an assumption. Instead, the license agreement provides that MedImmune must pay a royalty on sales of any product that would infringe Celltech's patent but for the license. The parties, therefore, left unresolved whether Synagis® would infringe Celltech's U.S. patent but for the license. Given the words of the license agreement and Celltech's concession that Synagis® does not fit within the literal scope of Celltech's patent claims, Celltech had no reasonable expectation of royalties from sales of Synagis®.

B. Prosecution History Estoppel Precluded Infringement Both Before and After the *Festo* Decision

Although it claims to be a victim of the *Festo* decision, Celltech's brief says remarkably little about the claims of its patent, the prosecution history that led to them, or why Celltech believes the outcome of its English case would have been any different before the *Festo* decision. The reason for this silence is that Celltech is simply attempting to recapture through the doctrine of equivalents subject matter that it was forced to relinquish during patent prosecution for reasons relating to patentability.

To the extent Celltech hopes to persuade this Court that it is a victim of injustice, a brief discussion of Celltech's patent is in order. Celltech's brief creates the misimpression that its patent provides a detailed blueprint that

identifies a precise sequence of more than 1300 individual amino acids (or "residues") needed to form a humanized antibody molecule. In fact, Celltech's patent claims a far more modest development that differed from the prior art with respect to only *two* of the more than 1300 residues that comprise an antibody molecule.

A "humanized" antibody is simply a mouse antibody that has been genetically altered to be more like the naturally occurring human antibody that fights a given disease. The purpose of this modification is to minimize the possibility that a human patient will reject an antibody generated by a mouse cell. The humanizing process involves altering DNA to replace certain residues in the mouse antibody with the residues that appear in the corresponding human antibody molecule. The prior art taught that it was critical for certain amino acids in the mouse antibody to remain unchanged, particularly the residues located in binding areas known as complementarity determining regions ("CDRs"), plus certain additional residue positions not located in the CDRs.

More specifically, Celltech's patent claims a humanized antibody molecule where mouse amino acids are retained at the CDRs, plus positions 6, 23, 24 and 49 of the antibody heavy chain. Celltech's patent does not specify which amino acids should appear at the claimed positions 6, 23, 24 and 49 (or any other positions). Instead, the only "invention" described by the claims is the identification of the four residue *positions* (in addition to the CDRs) that must be mouse residues, whatever amino acids they may be.

During prosecution, the Patent Office rejected Celltech's claims based on a humanized antibody described in a prior art reference by Riechmann, *et al.* In order to overcome this rejection, Celltech amended its claims to require *mouse* residues at positions 23 and 24, as compared to the antibody disclosed in the Riechmann reference which had *human* residues at positions 23 and 24. Celltech also argued, on several different occasions, that this amendment, which differed from the prior art by only *two* amino acids, distinguished the claims over the prior art. Even before *Festo*, Celltech would have been estopped from relying on the doctrine of equivalents to recapture the specific subject matter (*human* amino acids at positions 23 and 24) it had clearly and unequivocally surrendered during prosecution to avoid the prior art, even if *some* range of equivalents remained available. *See, e.g., Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995) ("[P]rosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent."). This principle is the foundation of the doctrine of prosecution history estoppel.

Having obtained its patent by distinguishing its "invention" from the prior art based on a difference with respect to just two amino acid positions, Celltech now attempts to minimize this same distinction in its suit against MedImmune. Celltech concedes that Synagis® does not have the claimed mouse residue at position 23. Instead, Synagis® has a human residue which is different from the mouse residue at that position. By no stretch of the imagination can a *change* of the residue at position 23 to a human amino acid constitute the equivalent of retaining a different mouse residue at position 23. This is particularly so in light of Celltech's claim amendments and repeated distinction of prior art antibodies that, like Synagis®, contained a human amino acid at position 23. Therefore, under *Warner-Jenkinson*, Celltech is precluded from relying on the doctrine of equivalents to cover humanized antibodies that have a human residue at position 23. ***This is the specific subject matter that Cell-***

tech surrendered during prosecution in response to prior art rejections, and it cannot be recaptured.

This is a classic case of prosecution history estoppel falling squarely within *Warner-Jenkinson* and its progeny. The practical effect of the *Festo* decision in a suit like Celltech's is to speed the dismissal of the case as a matter of law because no range of equivalents is available. Celltech's *amicus* brief appears to be an attempt to delay such a dismissal of its English action, which is stayed until this Court rules in the *Festo* case.

II. THE LITIGATION BETWEEN CELLTECH AND MEDIMMUNE IS AN EXAMPLE OF WHY *FESTO* SHOULD BE AFFIRMED

The facts of Celltech's case illustrate why the *Festo* decision provides much needed certainty for competitors seeking guidance on the scope of patents based on the prosecution history. A less rigorous application of prosecution history estoppel would allow patent holders to disavow their statements to the Patent Office in order to assert tenuous infringement claims that impose immense litigation costs on defendants to defeat them. In addition, uncertainty as to the scope of patent claims often leads potential licensees to take licenses and pay royalties as ransom to avoid litigation that may threaten important products. These concerns are even greater in the biotechnology field where unmeritorious claims may be unusually difficult to dismiss early in litigation due to the complicated technology involved and the lengthy prosecution histories that often precede the issuance of biotechnology patents.[5]

[5] Celltech's additional argument that *Festo* should not be applied "retroactively" is an affront to the doctrine of *stare decisis* that would create two different infringement regimes depending on the effective filing date of a patent application, which may itself be a hotly contested issue.

CONCLUSION

In what appears to be an attempt to prolong its English litigation, Celltech has created the misimpression that the fears of Judge Michel have come to fruition. However, Celltech's brief is misleading in several important respects. First, Celltech has falsely characterized MedImmune as a pirate of Celltech's technology, knowing full well that MedImmune developed Synagis® before Celltech's patent issued. Second, Celltech has misrepresented the scope of its own patent, suggesting much broader coverage than it actually has. Finally, Celltech failed to disclose its specific surrender of subject matter through arguments and claim amendments made during patent prosecution, giving rise to a prosecution history estoppel under pre-*Festo* authority. The only lesson to be learned from Celltech's *amicus* brief is the need for greater certainty with respect to the available scope of equivalents, particularly in the biotechnology field where patentees may assert years after the fact that unclaimed molecular structures were simply obvious variations of the claimed invention, even if such assertions fly in the face of what was surrendered during prosecution. The burden of clarity as to the scope of the claims belongs with the patentee. The certainty provided by *Festo* can curtail efforts, like Celltech's, to disavow statements made before the Patent Office in complicated fields like biotechnology.

Respectfully submitted,

HARVEY KURZWEIL
Counsel of Record
BRADFORD J. BADKE
HENRY J. RICARDO
DEWEY BALLANTINE LLP
1301 Avenue of the Americas
New York, New York 10019
(212) 259-8000

Counsel for Amicus Curiae
MedImmune, Inc.

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